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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,527	06/14/2002	Dirk Johannes Schaefer	0273-0004	4394

7590

10/24/2005

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,527

Applicant(s)

SCHAEFER ET AL.

Examiner

Lora E. Barnhart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-44 and 67 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-44 and 67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The reply received 9/1/05 amending claims 36, 40, and 41 and adding claim 67 with a Request for Continuing Examination is acknowledged. Claims 1-35 remain canceled, and claims 45-66 remain withdrawn. Claims 36-44 and 67 are currently under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Prior art references can be found in a prior Office action, unless otherwise noted.

Specification

The use of the trademarks "TRANSFECTAM", "FUGENE", "LIPOFECTAMINE 2000", "LIPOFECTIN", "ESCORT", and "GENE PULSER" has been noted in this application (see, for example, page 13, lines 6-8). These, and all trademarks, should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claim 36 is objected to because of the following informalities: The phrase "*in vitro*" should be italicized. Appropriate correction is required.

Claim 40 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

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dependent form, or rewrite the claim(s) in independent form. It is not clear what additional components or properties the composition of claim 40 possesses that the composition of claim 36 does not.

Claim 67 is objected to because of the following informalities: the comma after "as" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 36-44 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 36, which is drawn to a product, requires that said product comprise numerous components "prior to implantation." The claim does not recite implantation, and since the claim is drawn to a composition, it is not clear what this method step (*i.e.* implanting) is meant to imply. Clarification is required.

Additionally, claim 36 recites that the joint side "can" have contact with another joint part and that the anchor side "can" be used for anchoring the composition in the bone shaft, which is confusing. It is not clear whether these limitations are **necessarily** part of the claim. Clarification is required. Claims 38, 39, and 42 suffer similar defects and should also be clarified.

Because claims 37-44 and 67 depend from indefinite claim 36 and do not clarify the point of confusion, they must also be rejected under 35 U.S.C. 112, second paragraph.

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Claim 40 is further confusing in that it recites, "A **preformed** construct." First, the claim is drawn to a product, so references to method steps (*i.e.* forming) are confusing. In addition, it is not clear what time point is referenced by the term "preformed", or how this limitation affects the structure of the claimed composition. Clarification is required.

Claim Rejections - 35 USC § 102

Claims 36, 37, and 40 remain rejected under 35 U.S.C. 102(b) as being anticipated by U.S. '050 (Itay) taken in light of Thomas and Boden. The claims are drawn to a composition comprising at least one biocompatible carrier material, cartilaginous tissue, and osseous tissue, such that one surface of said composition consists of cartilaginous tissue and the opposite surface consists of osseous tissue. In some dependent claims, the composition's size and shape match the portion of the joint to be replaced.

As discussed previously, Itay teaches a composition produced *in vitro*, comprising a biocompatible carrier material (e.g. fibrinogen-based adhesive matrix) and chondrocytes, which are implanted into defective bones (Examples 1-3 and The Process). Additionally, the composition of Itay can be produced in any shape, including cylinders (column 4, line 68) and the precise shape of the damaged area (column 5, lines 3-4), and in any size (Example 3). Thomas is cited as evidence that synovial joints comprise two bones, each with a layer of articular cartilage coating the epiphyseal end (p. 1035) and that bone tissue comprises endothelial cells, *i.e.* blood vessels (page 249). Boden is cited as evidence that bone tissue contains growth factors (page 3, *e.g.*).

Applicant maintains that Itay does not teach a "joint construct" (Remarks, page 10). Applicant alleges that the term "joint construct" "connotes a definite structural articulation [that] cannot reasonably be associated with [Itay]" (*ibid.*). Applicant urges that the examiner reconsider the claims in light of the definition of "*in vitro*" provided in the specification (*ibid.*). Finally, applicant alleges that Itay does not teach "*in vitro* lateral sequestration of both types of cells and their appropriate tissue substances" (*ibid.*). These arguments have been fully considered, but they are not persuasive.

First, the term "joint construct" is not defined in the specification in terms of "a definite structural articulation", but rather in terms of its components (page 3, lines 2-7). The phrase "definite structural articulation" does not appear anywhere within the original specification. Indeed, the **claims** do not recite or reasonably imply a "definite structural articulation" either explicitly or in light of the specification as filed. The examiner queries applicant's allegation that U.S.'050 does not constitute prior art, since the specification clearly cites Itay as analogous art (page 1, lines 22-25).

The examiner agrees that the term "*in vitro*" is defined particularly in the specification as "a process [that] takes place outside the human or animal body" (page 2, lines 35-36) but points out that applicant is not claiming an *in vitro* construct, but rather a construct "produced at least partly *in vitro*." The scope clearly differs between the two phrases. In any case, as discussed previously, claim 36 is a product-by-process claim (see M.P.E.P. §2113), and, as such, the process limitations "produced at least partly *in vitro*" and "prior to implantation" are considered only to the extent that they affect the **structure** of the claimed composition.

Finally, applicant's arguments about "*in vitro* lateral sequestration" are confusing, since this phrase is not defined or even recited in the specification. Applicant's arguments seem to define this non-art-accepted phrase as a situation in which chondrocytes are present on one side of the composition and osteoblasts are present on the other (Remarks, page 11, paragraph 2), but the examiner points out that such a configuration is neither explicitly recited nor reasonably implied by the claims. The claim requires only that the composition have two "sides" but does not require that they be on opposing faces of the composition.

Claims 36-44 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Jakob et al. (1999, WO 99/21497; reference N, and German-to-English translation, reference O). The claims are drawn to a composition comprising at least one biocompatible carrier material, cartilaginous tissue, and osseous tissue, such that one surface of said composition consists of cartilaginous tissue and the opposite surface consists of osseous tissue. In some dependent claims, the composition's size and shape match the portion of the joint to be replaced. In some dependent claims, the composition has a circular cross-section. The page and paragraph numbers in this rejection refer to reference O, the English translation.

Jakob et al. teach a composition comprising bone adhered to cartilage that has been removed from a donor site (page 2, paragraph 3; Figures 1, 5-7, 9, and 10). The composition of Jakob et al. is a column of tissue comprising cartilage adhered firmly to bone (Figure 1; page 7, paragraph 1) and comprises a biocompatible carrier material in

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the respect that it is obtained from the patient's own body. Jakob et al. also teach a composition comprising cartilage cells cultured *in vitro* on bone-replacement material (page 5, paragraph 3; page 16, paragraph 3; Figures 11 and 12). The composition of Jakob et al. may have a circular cross-section (page 11, paragraph 4; page 12, paragraph 4; and Figures 13-16) or may have any shape (page 15, paragraph 3). The composition of Jakob et al. is cylindrical, thus fulfilling the requirements of claim 38, and comprises bone, which naturally comprises growth factors, thus fulfilling the requirements of claim 37.

The invention of Jakob et al. fulfills the requirements of claim 42 in that numerous tissue columns may be placed into a single defect such that their joint sides (*i.e.*, cartilage) are contacting one another (see, for example, Figure 5 and page 11, paragraph 3). The limitation that the anchor sides are in two different bone shafts has not been considered, since this is an optional limitation in the claims. The invention of Jakob et al. fulfills the requirements of claims 39, 43, and 44 in the respect that it comprises placing the tissue columns into live bone, which comprises ligaments and a joint capsule. The invention of Jakob et al. inherently comprises the limitations of claims 39, 43, and 44.

Claims 36-44 and 67 are product-by-process claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps." As such, the limitations "produced at least partly *in vitro*" and "prior to implantation" have been evaluated only to the extent that they affect the structure of the composition.

“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. “[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes

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put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Claims 36-41 are also rejected under 35 U.S.C. 102(b) as being anticipated by any of Mears (1985, U.S. Patent 4,553,272; reference A), Vacanti et al. (1998, U.S. Patent 5,736,372; reference B), and Caplan et al. (1986, U.S. Patent 4,609,551; reference C).

Mears teaches a composition comprising cartilage cells on a biocompatible carrier that is implanted into living bone and colonized by osseous tissue, which inherently comprises growth factors (Figure 2 and Example 1).

Vacanti et al. teaches a composition comprising cartilage cells on a biocompatible carrier that is implanted into living bone and colonized by osseous tissue, which inherently comprises growth factors (Examples 1-5, especially Example 5).

Caplan et al. teaches a composition comprising fibroblasts and a growth factor in a fibrin clot that is implanted into living bone and gives rise to both bone and cartilage (Example 4).

The cited claims are product-by-process claims; see M.P.E.P. § 2113 and discussion above. Because the process steps do not materially alter the structure of the claimed composition, Mears, Vacanti et al., and Caplan et al. anticipate the cited claims.

Claim Rejections - 35 USC § 103

Claims 36-38, 40-42, 44, and 67 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Itay, Thomas and Boden as applied to claims 36, 37, 40 and 41 above, and further in view of U.S. '296 (Johnson et al.). The claims are drawn to a composition as described above in which at least one cylindrical peg connects the composition to the bone shaft, and to a joint replacement which comprises two joint compositions that contact each other on their joint (cartilaginous) sides. Some dependent claims describe the shape of the composition. Itay does not teach a composition with a peg or a two-composition joint replacement.

As discussed in previous Office actions, Itay teaches a composition produced *in vitro*, comprising a biocompatible carrier material (e.g. fibrinogen-based adhesive matrix) and chondrocytes, which are implanted into defective bones. Additionally, the composition of Itay can be produced in any shape, including cylinders and the precise shape of the damaged area, and in any size. Thomas is cited as evidence that synovial joints comprise two bones, each with a layer of articular cartilage coating the epiphyseal end and that bone tissue comprises endothelial cells, i.e. blood vessels. Boden is cited as evidence that bone tissue contains growth factors.

As discussed in previous Office actions, Johnson et al. teaches a composition that is anchored into the bone shaft with a cylindrical peg (stems **16** and **19** in Figures 1-4). Johnson et al. also teaches a joint prosthesis comprising two components that engage with each other (Figures 1-4).

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The selection of cross-sectional shape clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Itay clearly states that the composition can have a variety of shapes (for example, cuboidal or cylindrical; column 4, lines 67-68), depending on the defect to be filled. A holding of obviousness over the cited claims is therefore clearly required.

The skilled artisan would have had a reasonable expectation of success in adding the cylindrical peg of Johnson et al. to the composition of Itay because the composition of Itay can have any shape or size (column 4, lines 50-52 and 67-68, and column 5, lines 3-6). The skilled artisan would have been motivated to use the peg of Johnson et al. in the composition of Itay for the expected benefit that a peg articulated into the bone shaft would produce a more secure fit than would two flat ends touching.

It would therefore have been obvious to a person of ordinary skill in the art to make the composition of Itay with the peg of Johnson et al. because the composition of Itay can be of any shape and size.

The skilled artisan would also have had a reasonable expectation of success in making a joint replacement comprising two compositions of Itay because the composition of Itay can be constructed in any shape and size (column 5, lines 3-6). The skilled artisan would have been motivated to make two of the compositions of Itay as in the joint replacement of Johnson et al. because Johnson et al. discloses that two-member joint replacements (i.e., those consisting of two portions, each of which covers one epiphyseal end in the joint, but which are not necessarily connected into one

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apparatus) present a problem in that the positioning of the two elements relative to each other so that they function properly is difficult (column 1, lines 32-34).

It would therefore have been obvious to a person of ordinary skill in the art to make a joint replacement using two of the compositions of Itay because Johnson et al. discloses that single-element joint replacements are more likely to function well than two-element joint replacements. Additionally, diseases such as rheumatoid arthritis often require the replacement of an entire joint, not just the end of one bone.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant alleges that the composition of Itay does not comprise the recited components "prior to implantation" (Remarks, page 12). Applicant further alleges that the composition of Itay taken in view of Thomas, Boden, and Johnson et al. cannot be made entirely *in vitro* (Remarks, page 13). These arguments have been fully considered, but they are not persuasive.

As discussed above, the claims are product-by-process claims (see M.P.E.P. §2113), and, as such, the process limitations "produced at least partly *in vitro*" and "prior to implantation" are considered only to the extent that they affect the **structure** of the claimed composition. The composition of Itay taken in view of Thomas, Boden, and Johnson et al. was constructed **at least partly *in vitro***, in accordance with the claims, and comprises the required components. The order of addition of these components is immaterial to the instant **product** claims.

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As discussed above, the examiner agrees that the term "*in vitro*" is defined particularly in the specification as "a process [that] takes place outside the human or animal body" (page 2, lines 35-36) but points out that applicant is not claiming an *in vitro* construct, but rather a construct "produced at least partly *in vitro*." The scope clearly differs between the two phrases. Applicant's arguments that the composition of Itay taken in view of Thomas, Boden, and Johnson et al. would require some *in vivo* culturing are unpersuasive because the claims do not exclude the possibility of *in vivo* growth, and because the claims are in product-by-process form. The method of production, as discussed above, is immaterial to the patentability of the product claims.

Claims 39 and 43 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Itay, Thomas, Boden and Johnson et al. as applied to claims 36-38 and 40-42, above, and further in view of U.S. '660 (Wevers et al.) and Dunn et al. The claims are drawn to biological joint compositions and replacements as described above, with the further limitation that the parts are connected together with ligamentous material. In some dependent claims, the joint replacement has a joint capsule. A joint capsule replacement can be constructed from the same materials as a ligament replacement (p.4 of specification). Itay and Johnson et al. do not teach compositions or replacements with ligaments or joint capsules.

As discussed in a previous Office action, Wevers et al. teaches a prosthetic ligament device comprising an elastic synthetic woven material, the device being securable to bones by use of bone screws (claim 1 and Figures). Dunn et al. teach a

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ligament analog prepared by seeding collagen scaffolds with fibroblasts that approximates the structure and strength of native ligament tissue. The artificial ligament of Dunn et al. remains viable after implantation into a joint.

A person of ordinary skill in the art would have had a reasonable expectation of success in connecting the parts of the joint replacements of Itay and Johnson et al. with the artificial ligaments of Wevers et al. and Dunn et al. because the artificial ligaments are disclosed as having properties similar to native ligament tissue. The skilled artisan would have been motivated to connect the apparatus parts of Itay and Johnson et al. with the ligament compositions of Wevers et al. and Dunn et al. for the expected benefit of strengthening the replaced joint. The artificial ligament of Wevers et al. in particular is disclosed as having elastic properties closely approximating natural ligament tissue (Figures 2 and 3), so joining the joint replacement elements with the ligament of Wevers et al. would more closely simulate a natural joint (see Abstract).

It would therefore have been obvious to a person of ordinary skill in the art to connect the compositions of Itay and Johnson et al. with ligament compositions in order to stabilize the replacement joint and to simulate more closely the natural properties of the joint.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant alleges that Itay does not teach a composition comprising the recited elements "prior to implantation" (Remarks, page 13) or "lateral sequestration of

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chondrogenic and osteogenic cells *in vitro*" (Remarks, page 14). These arguments have been fully considered, but they are not persuasive.

As discussed above, the claims are product-by-process claims (see M.P.E.P. §2113), and, as such, the process limitations "produced at least partly *in vitro*" and "prior to implantation" are considered only to the extent that they affect the **structure** of the claimed composition. The composition of Itay taken in view of Thomas, Boden, and Johnson et al. was constructed **at least partly *in vitro***, in accordance with the claims, and comprises the required components. The order of addition of these components is immaterial to the instant **product** claims.

As discussed above, applicant's arguments about "*in vitro* lateral sequestration" are confusing, since this phrase is not defined or even recited in the specification. Applicant's arguments seem to define this non-art-accepted phrase as a situation in which chondrocytes are present on one side of the composition and osteoblasts are present on the other (Remarks, page 11, paragraph 2), but the examiner points out that such a configuration is neither explicitly recited nor reasonably implied by the claims. The claim requires only that the composition have two "sides" but does not require that they be on opposing faces of the composition.

As discussed above, the examiner agrees that the term "*in vitro*" is defined particularly in the specification as "a process [that] takes place outside the human or animal body" (page 2, lines 35-36) but points out that applicant is not claiming an *in vitro* construct, but rather a construct "produced at least partly *in vitro*." The scope clearly differs between the two phrases. Applicant's arguments that the composition of Itay

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taken in view of Thomas, Boden, and Johnson et al. would require some *in vivo* culturing are unpersuasive because the claims do not exclude the possibility of *in vivo* growth, and because the claims are in product-by-process form. The method of production, as discussed above, is immaterial to the patentability of the product claims.

Conclusion

No claims are allowed. No claims are free of the art.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lora E Barnhart



SANDRA E. SAUCIER
PRIMARY EXAMINER